Notice of Allowability	Application No.	Applicant(s)	
	09/744,289	SZU ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *August 6, 2004*.

2. ☐ The allowed claim(s) is/are *13,43-51,20,52-57; now claims 1-17*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *8/9/2004* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. During a telephone conversation conducted on August 6, 2004, David Cash, Ph.D. an examiner's amendment was authorized.

2. The application has been amended as follows:

On page 1, after the title, please insert the following paragraph:

--PRIORITY CLAIM

This is a § 371 U.S. national stage of PCT/US98/14976, filed July 20, 1998.--

1-12. (canceled)

13. (currently amended) ~~The~~ A pharmaceutical composition, comprising:

about 25 μg of *E. coli* O157 O-specific polysaccharide covalently bound to a carrier, wherein the carrier is a B subunit of Shiga toxin 1, a B subunit of Shiga toxin 2, a non-toxic mutant Shiga toxin 1 holotoxin, or a non-toxic mutant Shiga toxin 2 holotoxin~~of claim 6~~, and

a pharmaceutically acceptable agent,

wherein injection into a human of a therapeutically effective amount of said composition ~~comprising 25 μg of *E. coli* O157 O-specific polysaccharide~~ produces in serum of said human bactericidal activity against *E. coli* O157 such that the bactercidial activity in the serum kills 50% or more of *E. coli* O157 at a serum dilution of 1,300:1 or more.

14-19. (canceled)

20. (currently amended) ~~The method of claim 19~~ A method of inducing in a mammal serum antibodies that are bacteriostatic or bactericidal to *E. coli* O157, comprising:

administering to said mammal, in a physiologically acceptable agent, a conjugate molecule comprising *E. coli* O157 O-specific polysaccharide covalently bound to a carrier, wherein the carrier is a B subunit of Shiga toxin 1, a B subunit of Shiga toxin 2, a non-toxic mutant Shiga toxin 1 holotoxin, or a non-toxic mutant Shiga toxin 2 holotoxin,

wherein said conjugate molecule is administered at a dose of about 5 micrograms to about 50 micrograms of *E. coli* O157 O-specific polysaccharide.

21-42. (canceled)

Please Add the following claims:

43. (new) The pharmaceutical composition of claim 13, wherein the *E. coli* O157 O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by means of a dicarboxylic acid dihydrazide linker.

44. (new) The pharmaceutical composition of claim 43, wherein the dicarboxylic acid dihydrazide is adipic acid dihydrazide.

45. (new) The pharmaceutical composition of claim 13, wherein the serum kills 50% or more of *E. coli* O157 at a serum dilution of 32,000:1 or more.

46. (new) The pharmaceutical composition of claim 13, wherein the serum kills 50% or more of *E. coli* O157 at a serum dilution of 64,000:1 or more.

47. (new) The pharmaceutical composition of claim 13, further comprising an adjuvant.

48. (new) The pharmaceutical composition of claim 13, wherein the carrier is the B subunit of Shiga toxin 1.

49. (new) The pharmaceutical composition of claim 13, wherein the carrier is the B subunit of Shiga toxin 2.

50. (new) The pharmaceutical composition of claim 13, wherein the carrier is the non-toxic mutant Shiga toxin 1 holotoxin.

51. (new) The pharmaceutical composition of claim 13, wherein the carrier is the non-toxic mutant Shiga toxin 2 holotoxin.

52. (new) The method of claim 20, wherein the *E. coli* O157 O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by means of a dicarboxylic acid dihydrazide linker.

53.(new) The method of claim 52, wherein the dicarboxylic acid dihydrazide is adipic acid dihydrazide.

54.(new) The method of claim 20, wherein the carrier is the B subunit of Shiga toxin 1.

55.(new) The method of claim 20, wherein the carrier is the B subunit of Shiga toxin 2.

56. (new) The method of claim 20, wherein the carrier is the non-toxic mutant Shiga toxin 1 holotoxin.

57. (new) The method of claim 20, wherein the carrier is the non-toxic mutant Shiga toxin 2 holotoxin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
August 9, 2004

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SUPERVISORY PATENT EXAMINER
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